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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,908	03/09/2001	Michael Stroble	833970.0002	2601

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	**PAPER NUMBER**
1614	23

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,908	STROBLE ET AL.	
	Examiner	Art Unit	
	Ray Henley	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-20* is/are rejected.

7)☒ Claim(s) *4,11,16 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-11 AND 13-20 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment and Declaration under 37 CFR 1.132 filed January 7, 2004 have been received and entered into the application. Accordingly, claims 2, 3, 5-11, 13-15, 17 and 18 have been amended. In view of the amendments, the rejection under 35 U.S.C. 112, second paragraph, as set forth in the previous Office action dated November 6, 2002 at page 2, is withdrawn.

Claim Objections

Claims 4, 11, 16 and 19 are objected to because of the following informalities:

Claims 4 and 16 are objected to because these claims are directed to "The flavoring agent of claim...", while the claims from which they depend are not directed to a flavoring agent, but rather a method for the analgesic treatment of a livestock animal.

In claim 11, line 1 "primiary" should read as ---primary---.

Claim 19 is objected to because it is grammatically incorrect. At line 1, after "weight;", the term ---and--- should be inserted.

Appropriate correction is required.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-11, 13, 15, 17, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5-11 are considered indefinite because the term "base" is ambiguous in that it may mean a substance that has the ability to turn litmus paper blue and react with acids to form salts or it may mean simply the supporting or foundation part of the solution. The metes and bounds of the subject matter for which applicants seek patent protection have not been set forth in accordance with 35 U.S.C. 112, second paragraph.

Claim 15 is considered indefinite because the point at which the step of adding a flavoring agent in the method of claim 13 has not been particularly pointed out.

In claims 13 and 17, it is unclear to what "a solution" refers. It is suggested that the claims be amended in a manner similar to the following in order to overcome this point of rejection:

"A method...administering to said animal an aqueous solution comprising..."

Claims 19 and 20 are considered indefinite because "a ratio of 1:10 by weight" does not make it clear as which ingredient is represented by the numerator and which by the denominator. In order to overcome this point of rejection, it is suggested that claim 19 be amended to read: "a ratio of ketoprofen to edible weak base of 1:10 by weight".

Also, claim 19 is incomplete because at line 4, a step of "adding a flavoring agent" is set forth. It has not been particularly point out to what the agent is added. The phrase "to the resulting mixture" should be inserted at line 4 of claim 19, after the word "agent" in order to overcome this point of rejection.

Claim Rejections - 35 USC § 103

I Claims 1, 2, 5-11, 13, 14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dondi et al. (U.S. Patent No. 5,624,682), already of record, for the reasons of

record as maintained in the previous Office action dated November 6, 2002 at page 2 as applied to claims 1, 5-11, 13 and 17. Claims 2, 13 and 18 are properly included above because at col. 1, lines 57-67, Dondi et al. teach the inclusion of a neutralizing agent to guarantee stability and tolerability of the formulation. The skilled artisan would have been motivated to select anyone of the claim designated basic ingredients as the neutralizing agent taught by Dondi et al. because ketoprofen was well known to be an acid (Dondi et al. at col. 1, lines 17-18) and it would have been readily appreciated that a basic ingredient would be needed to provide the neutralizing function as taught by Dondi et al. The selection of specific basic material from those known in the pharmaceutical art would have, in the absence of evidence to the contrary, been a matter well within the purview of the skilled artisan.

Applicants' arguments and the declaration of Michael A. Strobel have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicants have argued that Dondi teaches away from the present invention because the compositions of Dondi et al. suffer from precipitation problems and there is no motivation or suggestion of forming an oral, palatable, stable and safe solution of ketoprofen and an oral base in water for use in the mass administration to animals. In support of their position that the compositions of Dondi et al. suffer from precipitation problems, the declaration of Michael A. Strobel is offered to show that when the encapsulated solutions of Dondi et al. are diluted with water at a ratio of greater than 0.5 parts water to 1 part of the formulation, precipitation of the ketoprofen occurs and that the precipitated ketoprofen did not go back into solution after heating to 120 degrees Fahrenheit.

The Examiner does not find the arguments or declaration probative of non-obviousness however. Respecting the declaration, while the ingredients and amounts thereof used to form compositions of Examples 1-5 are set forth, no data has been presented showing the actual degree of ketoprofen precipitation that occurred with the addition of various quantities of water or the results that actually occurred following heating of the solution. The Declarant has merely offered conclusions that are not supported by actual data. In the absence of such data, the Examiner cannot make an independent analysis of the results which actually occurred.

Also, even if such data were present and did show the precipitation that is reported by Declarant, such would not diminish the propriety of the present rejection. The present rejection is not based on a conclusion that it would have been obvious to dilute the encapsulated ketoprofen solution of Dondi et al., but rather to employ the encapsulated solution in the presently claimed methods. The present claims contain no limitations that would distinguish it from the method that is taught and suggested by Dondi et al.

Concerning applicants' argument based upon the premise that the present invention is directed to forming an oral, palatable, stable and safe solution of ketoprofen and an oral base in water for use in the mass administration to animals, the Examiner does not agree with applicants' premise and therefore, the argument as a whole. The claims of an application define applicants' invention. Here, applicants' claims are directed to a method for the analgesic treatment of an animal which comprises, in the broadest sense, administering to said animal a pharmaceutically effective amount of a palatable solution of ketoprofen and an oral base in water. For the reasons

of record already advanced by the Examiner, this subject matter is *prima facie* obvious over the teachings of Dondi et al.

Accordingly, the claims are deemed properly rejected.

II Claims 19 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher (U.S. Patent No. 5,348,745), already of record, for the reasons of record as maintained in the previous Office action dated November 6, 2002 at pages 2 and 3.

Applicants' arguments have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicants have argued that in Daher, there is no motivation or suggestion of forming an oral, palatable, stable and safe solution of ketoprofen and an oral base in water for use in the mass administration to animals. The claims, however, are not directed to forming an oral, palatable, stable and safe solution of ketoprofen and an oral base in water for use in the mass administration to animals. Rather, claim 19 is directed merely to a method for preparing a water-soluble ingestible form of ketoprofen comprising the steps of mixing ketoprofen and an edible weak base in a ratio of 1:10 by weight and adding a flavoring agent. Daher teaches and/or suggest each of the claim limitations set forth in claims 19 and 20 and thus these claims remain properly rejected.

Newly Applied Art

Claims 1-11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markson (U.S. Patent No. 5,900,416).

Markson teaches an aqueous caffeine solution which may comprise caffeine, nicotinic acid (see the abstract), a basic buffer such as sodium bicarbonate, sodium hydroxide, potassium

carbonate and the like (col. 4, lines 11-18) and an effective amount of an analgesic capable of being topically absorbed through the skin or mucous membranes such as ketoprofen (col. 5, lines 20-32). Also, the composition may optionally contain artificial sweeteners including saccharin, cyclamate and aspartame may be present (col. 4, lines 53-61). Further, natural cherry may be present as a flavoring agent which inherently contains the sweetener "sugar" as required by present claims 4 and 16. The mere mixing of ingredients is demonstrated at cols. 6-7, Example 1-4.

Applicants should note that the agents in addition to ketoprofen taught by Markson are not excluded from the scope of the present claims because of the use of the transitional word "comprising" and thus can include other agents. Also, the claims recite "administering" and thus would encompass the topical application of the solution to the skin or mucous membrane as taught by Markson.

The differences between the above and the claimed subject matter lies in that Markson fails to highlight:

(1) the analgesic treatment of an animal, including livestock, for each of the inflammatory/pain conditions claimed, i.e., claims 5-10;

(2) each of the claimed bases, i.e., claims 2, 14 and 18;

(3) and the claimed proportion of ingredients.

However, to the skilled artisan, the claimed subject matter would have been obvious because;

(1) ketoprofen was a well known anti-inflammatory/analgesic agent and to employ such an agent to treat any specific inflammatory/pain condition of the type claimed, i.e., a condition

that could be treated through topical administration to the skin or the mucous membrane, would have been a matter well within the purview of the skilled artisan. The selection of any specific type of host, i.e., human, animal, livestock, to treat would also have been a matter well within the purview of the skilled artisan. Also, with respect to the claims not limited to the specific inflammatory/pain conditions, the skilled artisan would have been motivated to include a sweetener/flavoring agent in the topically applied composition because the solution may be applied to the mucous membranes, mucous membranes are in the oral cavity and a sweetener/flavoring agent would be seen as being useful in order to make the formulation as palatable as possible to ensure patient compliance and thus maximum therapeutic effects.

(2) At col. 4, lines 16-17, Markson teaches that "[e]ssentially any alkalizing agent may be employed.". The selection of any known alkalizing agent would have clearly been a matter well within the purview of the skilled artisan.

(3) The determination of the optimum ingredient amounts/ratios to employ also would have been a matter well within the purview of the skilled artisan and the artisan would have been motivated to do so in order to provide the most effective therapeutic agent possible.

Suggestion for Overcoming this Rejection

Applicants may wish to consider amending the claims so as to employ the transitional phrase "consisting essentially of" in order to overcome the present rejection. The Examiner believes such would overcome the rejection because Markson requires essential ingredients other than ketoprofen to be present in the solution. The above transitional phrase would exclude those agents of the prior art that are required by Markson, but not by applicants, i.e., caffeine and nicotinic acid. Should applicants choose to do so, care should be taken with the wording of the

dependent claims where an additional agent is added, i.e., claim 3. The phrase "further consisting essentially of" is not proper.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ray Henley
Primary Examiner
Art Unit 1614

Apr. 4, 2004